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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,774	02/04/2004	Hubert Barth	PC20545A	4105

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New York, NY 10017-5755

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary  
for Applications  
Under Accelerated Examination**

Application No.

10/771,774

Applicant(s)

BARTH ET AL.

Examiner

Tamthom N. Truong

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**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Since this application has been granted special status under the accelerated examination program,**  
**NO extensions of time under 37 CFR 1.136(a) will be permitted and a SHORTENED STATUTORY PERIOD FOR**  
**REPLY IS SET TO EXPIRE:**

**ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,**  
**FROM THE MAILING DATE OF THIS COMMUNICATION – if this is a non-final action or a *Quayle* action.**  
(Examiner: For **FINAL** actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

**Status**

- 1) ☒ Responsive to communication(s) filed on 5-30-06 (Election).  
2) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 3) ☒ Claim(s) 1-55 is/are pending in the application.  
3a) Of the above claim(s) 12-55 is/are withdrawn from consideration.  
4) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
5) ☒ Claim(s) 1,2 and 7-11 is/are rejected.  
6) ☒ Claim(s) 3-6 is/are objected to.  
7) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 8) ☐ The specification is objected to by the Examiner.  
9) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
10) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 11) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8-14-06.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election with traverse of Group 1 (claims 1-11) in the reply filed on 5-30-06 is acknowledged. The traversal is on the ground(s) that "prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner." This is not found persuasive for the following reasons:

- a. Groups I-VI are drawn to different processes of making compounds of different formulae. Although the quinazoline is the common core, each formula has different side chain which makes it distinct from others and requires a **separate search**. Also, each process has different sequential steps which demand more attention in determining relevancy of prior arts.
- b. Groups VII and VIII are drawn to compounds of formulae 49 and 45 which are intermediates, and might have different uses.
- c. It is maintained that the search and examination of 8 groups (or 55 claims) imposes serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 are considered.

Claims 12-55 are withdrawn as being drawn to the non-elected subject matter.

### *Claim Objections*

1. **Improper Multiple Dependent Claims:** Claims 3-6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to

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preceding claims in the alternative language. See MPEP § 608.01(n). Accordingly, the claims 3-6 have not been further treated on the merits.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependents thereon are rejected for reciting the limitation of “ester, amide or prodrug thereof” which has indefinite metes and bounds. It is unclear where the site is for the ester, amide or prodrug. Also, many substituents are in ester or amide form which makes it unclear if an additional ester or amide is intended by the claim.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Lack Written Description:** Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the step of converting the compound of formula I to a pharmaceutically acceptable ester, amide or prodrug thereof. However, the specification does not describe a possible ester, amide or prodrug. It also does not provide starting materials or reaction conditions for such a conversion. The specification only lists references for a description of prodrugs; however, such said references are not sufficient to support a process of making an ester, amide or a prodrug of the particularly claimed quinazoline.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Small et. al.** (J. Med. Chem. 2000, Vol. 43, pp. 1380-1397) in view of **Himmelsbach et. al.** (US

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6,627,634 B2). On page 1381, Scheme 2 describes a general process of making compound #18 (which is the same compound recited in the instant claim 11). Page 1390 details the process of making such a compound. Note, the term "comprising" in claim 1 does not exclude any steps leading up to formula 10.

The disclosed process differs from the claimed process by not having a G (or protecting) group on the amino (of the anilino). However, such a difference can be overcome by the teaching of Himmelsbach et. al. On columns 10-13, Himmelsbach et. al. describe a generic process of making a quinazoline compound with analogous substituents at the 4<sup>th</sup>, 6<sup>th</sup> and 7<sup>th</sup> positions. Then, on column 13, Himmelsbach et. al. discuss the possibility of having a protecting group on the amino, see the following excerpt:

In the reactions described hereinbefore, any reactive groups present such as hydroxy, carboxy, amino, alkylamino, or imino groups may be protected during the reaction by conventional protecting groups which are cleaved again after the reaction.

For example, a protecting group for a hydroxy group may be a trimethylsilyl, acetyl, benzoyl, methyl, ethyl, tert-butyl, trityl, benzyl, or tetrahydropyranyl group,

protecting groups for a carboxy group may be a trimethylsilyl, methyl, ethyl, tert-butyl, benzyl, or tetrahydropyranyl group, and

protecting groups for an amino, alkylamino, or imino group may be a formyl, acetyl, trifluoroacetyl, ethoxycarbonyl, tert-butoxycarbonyl, benzyloxycarbonyl, benzyl, methoxy-benzyl, or 2,4-dimethoxybenzyl group and additionally, for the amino group, a phthalyl group.

Any protecting group used is optionally subsequently cleaved for example by hydrolysis in an aqueous solvent, e.g., in water, isopropanol/water, acetic acid/water, tetrahydrofuran/water, or dioxane/water, in the presence of an acid such as trifluoroacetic acid, hydrochloric acid, or sulfuric acid, or in the presence of an alkali metal base such as sodium hydroxide or potassium hydroxide, or aprotically, e.g., in the presence of iodotrimethylsilane, at temperatures between 0° C. and 120° C., preferably at temperatures between 10° C. and 100° C.

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Note, not only Himmelsbach et. al. disclosing several protecting groups for an amino, but they also reveal reagents or reaction conditions to cleave such a group.

Thus, with the teaching of Himmelsbach et. al., the skilled chemist would have been motivated to modify the process of Small et. al. by having a protecting group on the amino (of the anilino).


Therefore, at the time that the invention was made, it would have been obvious to make a compound of formula I by combining the two teachings above.

No pending claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

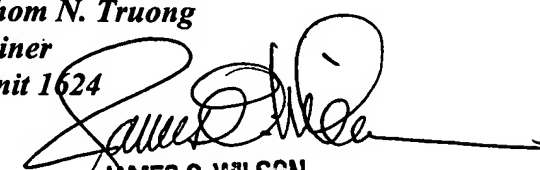
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Tamthom N. Truong  
Examiner  
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9-14-06

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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